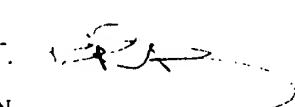


INTERNATIONAL COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference P4184/14793 CMH:RC | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
| International application No. PCT/AU 97/00304 | International filing date 16 May 1997 | Priority Date 17 May 1996 |
| International Patent Classification (IPC) or national classification and IPC Int. Cl.⁶ G01N 33/68, 33/551; C12N 1/00 | | |
| Applicant (1) WOMEN'S and CHILDREN'S HOSPITAL (2) MEIKLE, Peter J. et al | | |

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|--|--|---|-------------------------------------|---------------------|----|--------------------------|----------|-----|--------------------------|--|----|--------------------------|----------------------------|---|-------------------------------------|---|----|--------------------------|-------------------------|-----|--------------------------|--|------|-------------------------------------|---|
| 1. | This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. | This REPORT consists of a total of 4 sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 7 sheet(s). | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. This report contains indications relating to the following items: <table style="width: 100%; border: none;"> <tr> <td style="width: 5%;">I</td> <td style="width: 5%;"><input checked="" type="checkbox"/></td> <td>Basis of the report</td> </tr> <tr> <td>II</td> <td><input type="checkbox"/></td> <td>Priority</td> </tr> <tr> <td>III</td> <td><input type="checkbox"/></td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>IV</td> <td><input type="checkbox"/></td> <td>Lack of unity of invention</td> </tr> <tr> <td>V</td> <td><input checked="" type="checkbox"/></td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement</td> </tr> <tr> <td>VI</td> <td><input type="checkbox"/></td> <td>Certain documents cited</td> </tr> <tr> <td>VII</td> <td><input type="checkbox"/></td> <td>Certain defects in the international application</td> </tr> <tr> <td>VIII</td> <td><input checked="" type="checkbox"/></td> <td>Certain observations on the international application</td> </tr> </table> | | I | <input checked="" type="checkbox"/> | Basis of the report | II | <input type="checkbox"/> | Priority | III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | IV | <input type="checkbox"/> | Lack of unity of invention | V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement | VI | <input type="checkbox"/> | Certain documents cited | VII | <input type="checkbox"/> | Certain defects in the international application | VIII | <input checked="" type="checkbox"/> | Certain observations on the international application |
| I | <input checked="" type="checkbox"/> | Basis of the report | | | | | | | | | | | | | | | | | | | | | | | |
| II | <input type="checkbox"/> | Priority | | | | | | | | | | | | | | | | | | | | | | | |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | | | | | | | | | | | | | | | | | |
| IV | <input type="checkbox"/> | Lack of unity of invention | | | | | | | | | | | | | | | | | | | | | | | |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement | | | | | | | | | | | | | | | | | | | | | | | |
| VI | <input type="checkbox"/> | Certain documents cited | | | | | | | | | | | | | | | | | | | | | | | |
| VII | <input type="checkbox"/> | Certain defects in the international application | | | | | | | | | | | | | | | | | | | | | | | |
| VIII | <input checked="" type="checkbox"/> | Certain observations on the international application | | | | | | | | | | | | | | | | | | | | | | | |

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| Date of submission of the demand 16 December 1997 | Date of completion of the report 3 April 1998 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929 | Authorized Officer  ISOBEL TYSON Telephone No. (02) 6283 2563 |

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

☐ the international application as originally filed.

☒ the description, pages 1-46, as originally filed,
 pages , filed with the demand,
 pages , filed with the letter of ,
 pages , filed with the letter of .

☒ the claims, Nos. , as originally filed,
 Nos. , as amended under Article 19,
 Nos. , filed with the demand,
 Nos. 1-51, filed with the letter of 11 March 1998,
 Nos. , filed with the letter of .

☐ the drawings, sheets/fig , as originally filed,
 sheets/fig , filed with the demand,
 sheets/fig , filed with the letter of ,
 sheets/fig , filed with the letter of .

2. The amendments have resulted in the cancellation of:

☐ the description, pages

☒ the claims, Nos. 52

☐ the drawings, sheets/fig

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Claims 1-51 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims 1-51 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1-51 | YES |
| | Claims | NO |

2. Citations and explanations**NOVELTY (N), INVENTIVE STEP (IS): Claims 1-51**

In light of the proposed amendments, the invention of the present application can now be considered novel and possessing an inventive step, wherein the invention is neither taught towards nor disclosed in the documents cited earlier in the ISR. This is due in particular to the specification of the LSD marker being "an enzyme, a polypeptide or a protein which is associated with the occurrence, development or onset of said LSD, or an immunologically interactive homologue, analogue or derivative thereof", thus removing the sialic acid of the citations from the definition of the LSD marker.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

On page 4, references to MPS IIIIA and MPS IIIC appear to be incorrect. In Table 1 on page 26 there are represented MPS IIIA and MPS IIIC, which would appear to be correct.